

IV. Robust Summaries of Existing Data

PHYSICO-CHEMICAL PROPERTY – OCTANOL/WATER PARTITION COEFFICIENT	
<u>Test Substance</u>	
Chemical Name	Tall oil fatty acid
CAS #	61790-12-3
Remarks	This substance is also referred to as TOFA in the test plan for Tall Oil Fatty Acids and Related Substances.
<u>Method</u>	
Method/Guideline followed	Testing was conducted according to OECD Test Method 117, "Partition Coefficient (n-Octanol/Water) High Performance Liquid Chromatograph (HPLC) Method"
Test Type	Partition coefficient
GLP (Y/N)	Y
Year (Study Performed)	1993
Test conditions	Tall oil fatty acid was dissolved in methanol and the solution was analyzed by HPLC with UV detection using a mobile phase of methanol:buffer (3:1) at pH 2 and pH 7.5. A mixture of seven materials with known log P_{ow} values was used for reference.
<u>Results</u>	At pH 2, the log P_{ow} values of seven components in tall oil fatty acid were 4.4, 7.0, 7.3, 7.5, 7.7, 8.0, and 8.3. At pH 7.5, the log K_{ow} values of six components in tall oil fatty acid were 3.6, 3.8, 4.2, 4.5, 4.7, and 7.4.
<u>Data Quality</u>	Reliable without restrictions – Klimisch Code 1a
<u>Reference</u>	Dybdahl, H.P. 1993. Determination of log P_{ow} for single components in tall oil fatty acid. GLP Study No. 408335/472. Water Quality Institute, Horsholm, Denmark.

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Robust Summaries of Existing Data

PHYSICO-CHEMICAL PROPERTY – OCTANOL/WATER PARTITION COEFFICIENT	
<u>Test Substance</u>	
Chemical Name	Tall oil fatty acid
CAS #	61790-12-3
Remarks	This substance is also referred to as TOFA in the test plan for Tall Oil Fatty Acids and Related Substances.
<u>Method</u>	
Method/Guideline followed	Testing was conducted according to OECD Test Method 117, <i>"Partition Coefficient (n-Octanol/Water) High Performance Liquid Chromatograph (HPLC) Method"</i>
Test Type	Partition coefficient
GLP (Y/N)	Y
Year (Study Performed)	1993
Test conditions	Tall oil fatty acid was dissolved in methanol and the solution was analyzed by HPLC with UV detection using a mobile phase of methanol:buffer (3:1) at pH 2 and pH 7.5. A mixture of seven materials with known log P_{ow} values was used for reference.
<u>Results</u>	At pH 2, the log P_{ow} values of seven components in tall oil fatty acid were 4.4, 7.0, 7.3, 7.5, 7.7, 8.0, and 8.3. At pH 7.5, the log K_{ow} values of six components in tall oil fatty acid were 3.6, 3.8, 4.2, 4.5, 4.7, and 7.4.
<u>Data Quality</u>	Reliable without restrictions – Klimisch Code 1a (Note, however, that test results do not necessarily reflect partitioning of the complex mixture, but rather of certain components.)
<u>Reference</u>	Dybdahl, H.P. 1993. Determination of log P_{ow} for single components in tall oil fatty acid. GLP Study No. 408335/472. Water Quality Institute, Horsholm, Denmark.

PHYSICO-CHEMICAL PROPERTY – OCTANOL/WATER PARTITION COEFFICIENT	
<u>Test Substance</u>	
Chemical Name	Tall oil fatty acids, low boiling
CAS #	65977-03-7
Remarks	This substance is also referred to as tall oil heads in the test plan for Tall Oil Fatty Acids and Related Substances.
<u>Method</u>	
Method/Guideline followed	Testing was conducted according to OECD Test Method 117, <i>"Partition Coefficient (n-Octanol/Water) High Performance Liquid Chromatograph (HPLC) Method"</i>
Test Type	Partition coefficient
GLP (Y/N)	Y
Year (Study Performed)	1993
Test conditions	Tall oil heads was dissolved in methanol and the solution was analyzed by HPLC with UV detection using a mobile phase of methanol:buffer (3:1) at pH 2 and pH 7.5. A mixture of seven materials with known log P _{ow} values was used for reference.
<u>Results</u>	At pH 2, the log P _{ow} values of nine components in tall oil heads were 4.4, 6.7, 6.9, 7.0, 7.2, 7.2, 7.4, 7.7, and 7.8. At pH 7.5, the log P _{ow} values of seven components in tall oil heads were 4.6, 6.5, 6.9, 6.9, 7.3, 7.4, and 8.0.
<u>Data Quality</u>	Reliable without restrictions – Klimisch Code 1a (Note, however, that test results do not necessarily reflect partitioning of the complex mixture, but rather of certain components.)
<u>Reference</u>	Dybdahl, H.P. 1993. Determination of log Pow for single components in tall oil heads. GLP Study No. 408335/474. Water Quality Institute, Horsholm, Denmark.

PHYSICO-CHEMICAL PROPERTY – OCTANOL/WATER PARTITION COEFFICIENT	
<u>Test Substance</u>	
Chemical Name	Fatty acids, C16-C18 and C18 unsaturated, branched and linear
CAS #	68955-98-6
Remarks	This substance is also referred to as monomer acid in the test plan for Tall Oil Fatty Acids and Related Substances.
<u>Method</u>	
Method/Guideline followed	Testing was conducted according to Method A8 of Commission Directive 92/69/EEC
Test Type	Partition coefficient
GLP (Y/N)	N
Year (Study Performed)	1994
Test conditions	Not specified
<u>Results</u>	Fatty acids, C16 - C18 and C18 unsaturated, branched and linear had a partition coefficient of 7.93×10^4 at 25°C, or a Log ₁₀ P _{ow} of 4.90.
<u>Data Quality</u>	Reliable with restrictions – Klimisch Code 2a (Note, however, that test results do not necessarily reflect partitioning of the complex mixture, but rather of certain components.)
<u>Reference</u>	Mullee, D.M. 1994. Determination of partition coefficient. Project ID No. 508/027. SafePharm Laboratories Ltd., Derby, England.

ENVIRONMENTAL FATE – BIODEGRADATION	
<u>Test Substance</u>	
Chemical Name	Tall oil fatty acid
CAS #	61790-12-3
Remarks	This substance is also referred to as TOFA in the test plan for Tall Oil Fatty Acids and Related Substances.
<u>Method</u>	
Method/Guideline followed	Testing was conducted according to OECD Test Method 301 D, <i>"Ready Biodegradability: Closed Bottle Test"</i>
Test Type (aerobic/anaerobic)	Aerobic
GLP (Y/N)	Y
Year (Study Performed)	1993
Contact time	28 days
Inoculum	Secondary effluent from Rungsted Treatment plant
Test conditions	<p>Inoculum: Secondary effluent was collected from Rungsted Treatment plant.</p> <p>Concentration of test chemical: A stock solution of the test material (2 g/L) was prepared in demineralized water by ultra sonication for 5 minutes.</p> <p>Test Setup: Test medium was prepared by adding 1 mL each of four solutions (potassium phosphate, magnesium sulfate, calcium chloride, ferric chloride) to 1 liter of demineralized water, which was aerated to an initial oxygen concentration of 9 mg O₂/L and inoculated with 1 drop of secondary effluent per liter. The test article was added at 2 mg/L to a part of the inoculated test medium, equivalent to a chemical oxygen demand of 5.03 mg O₂/L. Sodium benzoate, the reference compound, was added at 2 mg/L to another part of the inoculated medium (to assess the activity of the inoculum), equivalent to a theoretical oxygen demand of 3.34 mg O₂/L. Both the test and reference articles (2 mg/L) were added to a third part of the inoculated medium (to assess possible inhibitory effects of the test article), at a theoretical oxygen demand of 8.37 mg O₂/L. Blank controls were prepared using the inoculated medium without test or reference materials. After the samples were prepared, the medium was transferred to calibrated respirometric bottles (BOD bottles), and placed in the dark at 20°C. The study was performed in triplicate.</p> <p>Sampling frequency: Samples were collected for BOD analysis on days 0, 7, 14, 21, and 28.</p> <p>Controls: Yes.</p> <p>Method of calculating oxygen demand: Oxygen demand was calculated as the difference between the measured oxygen concentrations at time t and the start of the test. Biological oxygen demand was calculated by subtracting the oxygen demand for the blank controls from the oxygen demand in the bottles containing test and reference compounds.</p>

<u>Results</u>	
Degradation % after time	50% after 7 days and 56% after 28 days (test article); 63% after 7 days and 77% after 28 days (sodium benzoate)
<u>Conclusions</u>	The biological oxygen demand for tall oil fatty acid was 50 and 56% of the theoretical oxygen demand after 7 and 28 days, respectively. The rapid oxygen consumption in the first week and the total oxygen demand at the termination of the experiment indicate that the test material was dominated by readily biodegradable compounds. Tall oil fatty acid did not inhibit the respiratory activity of the inoculum.
<u>Data Quality</u>	Reliable without restrictions– Klimisch Code 1a
<u>Reference</u>	Madsen, T. 1993. Biodegradation of tall oil fatty acid. GLP Study No. 308067/472. Water Quality Institute, Horsholm, Denmark.

ENVIRONMENTAL FATE – BIODEGRADATION	
<u>Test Substance</u>	
Chemical Name	Tall oil fatty acid
CAS #	61790-12-3
Remarks	This substance is also referred to as TOFA in the test plan for Tall Oil Fatty Acids and Related Substances.
<u>Method</u>	
Method/Guideline followed	Testing was conducted according to OECD Test Method 301 F, <i>"Manometric respiratory test for biological degradation"</i>
Test Type (aerobic/anaerobic)	Aerobic
GLP (Y/N)	Y
Year (Study Performed)	1999
Contact time	28 days
Inoculum	Activated sludge from a municipal sewage treatment plant
Test conditions	<p>Inoculum: Activated sludge from the municipal sewage treatment plant in Reutlingen was washed twice with tap water and centrifuged.</p> <p>Concentration of test chemical: A stock solution of the test material (101.5 mg/L) was prepared.</p> <p>Test Setup: Mineral medium was prepared by adding 10 mL of a potassium phosphate solution and 1 mL each of three other solutions (magnesium sulfate, calcium chloride, ferric chloride) to make a total volume of 1 liter in demineralized water. Six flasks were prepared: two of the test article in mineral medium with inoculum (24 mg/L); two of the mineral medium plus the inoculum (24 mg/L); one of the reference substance [sodium benzoate (98.5 mg/L)] with inoculum (24 mg/L); and one of the test article in water with sterilized medium.</p> <p>Sampling frequency: Samples were collected for analysis on days 14 and 28.</p> <p>Controls: Yes.</p> <p>Method of calculating oxygen demand: Biological oxygen demand was calculated by subtracting the oxygen demand for the blank controls from the oxygen demand in the flasks containing test and reference compounds.</p>
<u>Results</u>	
Degradation % after time	84% after 28 days (test article); 97% after 28 days (sodium benzoate)
<u>Conclusions</u>	
Eighty-four percent of tall oil fatty acid was biodegraded after 28 days indicating that the organic portion of the test material was readily biodegradable.	
<u>Data Quality</u>	
Reliable without restrictions– Klimisch Code 1a	
<u>Reference</u>	
Aniol, S. 1999. Biological degradation (Manometric respirometry test). STZ Project No. 03/99. Steinbeis-Transferzentrum Angewandte und Umwelt-Chemie, Reutungen.	

ENVIRONMENTAL FATE – BIODEGRADATION	
<u>Test Substance</u>	
Chemical Name	Tall oil fatty acid
CAS #	61790-12-3
Remarks	This substance is also referred to as TOFA in the test plan for Tall Oil Fatty Acids and Related Substances.
<u>Method</u>	
Method/Guideline followed	Testing was conducted according to the CO ₂ Evolution Test (Modified Sturm Test), EPA guideline number OPPTS 853.110, "Ready Biodegradability"
Test Type (aerobic/anaerobic)	Aerobic
GLP (Y/N)	N
Year (Study Performed)	1994
Contact time	29 days
Inoculum	Activated sludge from the Severn Trent water sewage treatment plant
Test conditions	<p>Inoculum: Activated sludge microorganisms were obtained from the Severn Trent water sewage treatment plant at Belper, Derbyshire. A 1% inoculum was prepared.</p> <p>Concentration of test chemical: The test material was used at a concentration of 20 mg/L.</p> <p>Test Setup: Culture medium was prepared by adding 10 mL of a potassium phosphate solution and 1 mL each of three other solutions (magnesium sulfate, calcium chloride, ferric chloride) to a final volume of 1 liter in purified water. Twenty-four hours prior to study initiation, vessels were filled with 2400 mL of culture medium and 30 mL of inoculum and aerated over night. On day 0 of the study, the test and reference material (sodium benzoate, 10 mg/L) were added and the total volume was increased to 3 liters. The following series of vessels was prepared: culture medium with inoculum; culture medium with inoculum and sodium benzoate; and culture medium with inoculum and test material. The CO₂ absorption bottles were connected to the outlet and were sealed. CO₂-free air was bubbled through the solution and they were stirred continuously. All experiments were performed in the dark at 20 to 22°C.</p> <p>Sampling frequency: Samples (2 mL) were collected from the first CO₂ absorber vessel on days 0, 1, 2, 3, 6, 8, 10, 14, 16, 18, 20, 22, 24, 27, 28, and 29, and from the second absorber on days 0 and 29.</p> <p>Controls: Yes.</p> <p>Analysis: Samples from the CO₂ absorbers were injected into the inorganic carbon channel of the total carbon analyzer for direct analysis of evolved CO₂. The analyses were conducted in triplicate.</p>
Degradation % after time	74% after 28 days (test article); 80% after 28 days (sodium benzoate)
<u>Conclusions</u>	
The test article was degraded 74% after 28 days and sodium	

	benzoate was degraded 80% after 28 days. Under the conditions of the OECD guidelines, the test article cannot be considered to be readily biodegradable.
<u>Data Quality</u>	Reliable without restrictions– Klimisch Code 1b
<u>Reference</u>	Sewell, I.G. 1994. Assessment of ready biodegradability using the CO ₂ evolution test (modified Sturm test). Project No. 508/28. SafePharm Laboratories Ltd., Derby, England.

ENVIRONMENTAL FATE – BIODEGRADATION	
<u>Test Substance</u>	
Chemical Name	Tall oil fatty acids, low boiling
CAS #	65997-03-2
Remarks	This substance is also referred to as tall oil heads in the test plan for Tall Oil Fatty Acids and Related Substances.
<u>Method</u>	
Method/Guideline followed	Testing was conducted according to OECD Test Method 301 D, <i>"Ready Biodegradability: Closed Bottle Test"</i>
Test Type (aerobic/anaerobic)	Aerobic
GLP (Y/N)	Y
Year (Study Performed)	1993
Contact time	28 days
Inoculum	Secondary effluent from Rungsted Treatment plant
Test conditions	<p>Inoculum: Secondary effluent was collected from Rungsted Treatment plant.</p> <p>Concentration of test chemical: A stock solution of the test material (2 g/L) was prepared in demineralized water by ultra sonication for 5 minutes.</p> <p>Test Setup: Test medium was prepared by adding 1 mL each of four solutions (potassium phosphate, magnesium sulfate, calcium chloride, ferric chloride) to 1 liter of demineralized water, which was aerated to an initial oxygen concentration of 9 mg O₂/L and inoculated with 1 drop of secondary effluent per liter. The test article was added at 2.4 mg/L to a part of the inoculated test medium, equivalent to a chemical oxygen demand of 4.94 mg O₂/L. Sodium benzoate, the reference compound, was added at 2 mg/L to another part of the inoculated medium (to assess the activity of the inoculum), equivalent to a theoretical oxygen demand of 3.34 mg O₂/L. Both the test and reference articles were added to a third part of the inoculated medium (to assess possible inhibitory effects of the test article), at a theoretical oxygen demand of 8.28 mg O₂/L. Blank controls were prepared using the inoculated medium without test or reference materials. After the samples were prepared, the medium was transferred to calibrated respirometric bottles (BOD bottles), and placed in the dark at 20°C. The study was performed in triplicate.</p> <p>Sampling frequency: Samples were collected for BOD analysis on days 0, 7, 14, 21, and 28.</p> <p>Controls: Yes.</p> <p>Method of calculating oxygen demand: Oxygen demand was calculated as the difference between the measured oxygen concentrations at time t and the start of the test. Biological oxygen demand was calculated by subtracting the oxygen demand for the blank controls from the oxygen demand in the bottles containing test and reference compounds.</p>

<u>Results</u>	
Degradation % over time	33% after 7 days and 41% after 28 days (test article); 63% after 7 days and 77% after 28 days (sodium benzoate)
<u>Conclusions</u>	The biological oxygen demand for tall oil heads was 33 and 41% of the theoretical oxygen demand after 7 and 28 days, respectively. These results indicate that the test material contains readily biodegradable and recalcitrant compounds. Tall oil heads did not inhibit the respiratory activity of the inoculum.
<u>Data Quality</u>	Reliable without restrictions– Klimisch Code 1a
<u>Reference</u>	Madsen, T. 1993. Biodegradation of tall oil heads. GLP Study No. 308067/474. Water Quality Institute, Horsholm, Denmark.

ENVIRONMENTAL FATE – BIODEGRADATION	
<u>Test Substance</u>	
Chemical Name	Fatty acids, C16 - C18 and C18 unsaturated, branched and linear
CAS #	68955-98-6
Remarks	This substance is also referred to as monomer acid in the test plan for Tall Oil Fatty Acids and Related Substances.
<u>Method</u>	
Method/Guideline followed	Testing was conducted according to the CO ₂ Evolution Test (Modified Sturm Test), EPA guideline number OPPTS 853.110, "Ready Biodegradability"
Test Type (aerobic/anaerobic)	Aerobic
GLP (Y/N)	N
Year (Study Performed)	1994
Contact time	29 days
Inoculum	Activated sludge from the Severn Trent water sewage treatment plant
Test conditions	<p>Inoculum: Activated sludge microorganisms were obtained from the Severn Trent water sewage treatment plant at Belper, Derbyshire. A 1% inoculum was prepared.</p> <p>Concentration of test chemical: The test material was used at a concentration of 20 mg/L.</p> <p>Test Setup: Culture medium was prepared by adding 10 mL of a potassium phosphate solution and 1 mL each of three other solutions (magnesium sulfate, calcium chloride, ferric chloride) to a final volume of 1 liter in purified water. Twenty-four hours prior to study initiation, vessels were filled with 2400 mL of culture medium and 30 mL of inoculum and aerated over night. On day 0 of the study, the test and reference material (sodium benzoate, 10 mg/L) were added and the total volume was increased to 3 liters. The following series of vessels was prepared: culture medium with inoculum; culture medium with inoculum and sodium benzoate; and culture medium with inoculum and test material. The CO₂ absorption bottles were connected to the outlet and were sealed. CO₂-free air was bubbled through the solution and they were stirred continuously. All experiments were performed in the dark at 21 to 22°C.</p> <p>Sampling frequency: Samples (2 mL) were collected from the first CO₂ absorber vessel on days 0, 1, 2, 3, 6, 8, 10, 12, 14, 16, 20, 22, 24, 27, 28, and 29, and from the second absorber on days 0 and 29.</p> <p>Controls: Yes.</p> <p>Analysis: Samples from the CO₂ absorbers were injected into the inorganic carbon channel of the total carbon analyzer for direct analysis of evolved CO₂. The analyses were conducted in triplicate.</p>
<u>Results</u>	
Degradation % after time	67% after 28 days (test article); 87% after 28 days (sodium benzoate)

<u>Conclusions</u>	The test article was degraded 67% after 28 days. Under the conditions of the OECD guidelines, it cannot be considered to be readily biodegradable.
<u>Data Quality</u>	Reliable without restrictions– Klimisch Code 1b
<u>Reference</u>	Sewell, I.G. 1994. Assessment of ready biodegradability using the CO2 evolution test (modified Sturm test). Project No. 508/23. SafePharm Laboratories Ltd., Derby, England.

ENVIRONMENTAL FATE – BIODEGRADATION	
<u>Test Substance</u>	
Chemical Name	Tall oil fatty acids, potassium salt
CAS #	61790-44-1
Remarks	This substance is referred to as tall oil fatty acids, potassium salt, in the test plan for Tall Oil Fatty Acids and Related Substances.
<u>Method</u>	
Method/Guideline followed	Testing was conducted according to a modified OECD test for ready biodegradability, EPA guideline number OPPTS 853.110, "Ready Biodegradability"
Test Type (aerobic/anaerobic)	Aerobic
GLP (Y/N)	Y
Year (Study Performed)	1991
Contact time	28 days
Inoculum	Activated sludge from Bergen County sewage treatment plant
Test conditions	<p>Inoculum: Activated sludge from Bergen County sewage treatment plant was mixed with soil extract and surface water to prepare the inoculum.</p> <p>Concentration of test chemical: The test article was tested at a concentration of 20 to 25 ppm.</p> <p>Test Setup: OECD test medium was used. Aniline was the reference material and was tested at a concentration of 20 to 25 ppm. The experiments were performed in the dark at 20 to 25°C.</p> <p>Sampling frequency: Samples were collected for analysis on days 0, 7, 14, 21, and 28.</p> <p>Controls: Yes.</p> <p>Method of calculating degradation: The mean initial concentration of soluble organic carbon (SOC) in the controls is subtracted from the initial concentration in the test sample. From this is subtracted, the mean initial concentration of SOC in the test and control samples at time t. This value is divided by the mean initial concentration of SOC in the controls subtracted from the initial concentration in the test sample.</p>
<u>Results</u>	
Degradation % after time	79% after 28 days (test article); 97% after 28 days (aniline)
<u>Conclusions</u>	
The test material degraded 79% and is considered to be readily biodegradable as defined by OECD.	
<u>Data Quality</u>	
Reliable without restrictions– Klimisch Code 1b	
<u>Reference</u>	
Drozdowski, D. 1991. Modified OECD test for ready biodegradability of [product name deleted] tall oil fatty acid potassium salt. Report No. 063383-1. United States Testing Company, Inc., Hoboken, New Jersey.	

ACUTE TOXICITY – ORAL	
<u>Test substance</u>	
Chemical Name	Tall oil fatty acid
CAS #	61790-12-3
Remarks	This substance is also referred to as TOFA in the test plan for Tall Oil Fatty Acids and Related Substances.
<u>Method</u>	
Method/Guideline followed	Test procedure was consistent with OECD Test Method 401, "Acute Oral Toxicity"
GLP (Y/N)	Y
Year (Study Performed)	1983
Species	Rat
Strain	Sprague-Dawley
Route of administration	Oral
Dose levels	10,000 mg/kg
Sex and number/group	5 male and 5 female rats
Frequency of treatment	Single oral gavage
Duration of test	14 day observation post-treatment
Control group (Y/N)	N
<u>Result</u>	
Acute Oral LD ₅₀	>10,000 mg/kg
<u>Detailed Summary</u>	
	Sprague-Dawley rats (n = 5/sex) received a single oral (gavage) dose of 10,000 mg/kg of fatty acid, tall oil (CAS #61790-12-3) and were observed for 14 days. Parameters evaluated included clinical signs, mortality, body weight, and gross pathology. None of the animals died. One hour post-dosing, piloerection was observed in one male and abnormal stance was observed in one male and one female. By four hours, these effects had resolved. No body weight effects were observed. Gross necropsy revealed no treatment-related effects. The acute oral LD ₅₀ was greater than 10,000 mg/kg.
<u>Data Quality</u>	
Valid without restriction – Klimisch Code 1a	
<u>Reference</u>	
Mallory, V.T. 1983. Acute oral toxicity study in rats: fatty acid [product name deleted]. Study No. PH 402-AC-009-83. Pharmakon Research International, Inc., Waverly, Pennsylvania.	

REPEAT DOSE TOXICITY	
<u>Test substance</u>	
Chemical Name	Tall oil fatty acid
CAS #	61790-12-3
Remarks	This substance is also referred to as TOFA in the test plan for Tall Oil Fatty Acids and Related Substances.
<u>Method</u>	
Method/Guideline followed	Test procedure was similar to OECD Test Method 407, " <i>Repeat Dose 28-Day Oral Toxicity Study in Rodents</i> ," but failed to collect data on several parameters (hematology, clinical chemistry, histopathology) and was only conducted in male animals.
Year	1969
GLP (Y/N)	N (pre-GLP)
Species	Rat
Strain	Sprague-Dawley
Sex	Male
Route of Administration	Oral, diet
Exposure Period	28 days
Frequency of Treatment	Daily
Post-exposure observation period	None
Dose Levels	0, 15, 30, and 60% of total calories
Control group (Y/N)	Y
<u>Results</u>	
NOAEL:	15%
<u>Detailed Summary</u>	
	Male Sprague-Dawley rats (n = 10/group) were fed diets containing tall oil acid distillate (CAS #61790-12-3) as 0, 15, 30 or 60% of the total calories for four weeks. Parameters evaluated included mortality, body weight, and food consumption. One animal treated with 15% died (day of death not specified) and all animals treated with 60% died within four days of dose initiation. It is unlikely that this single death was a treatment related effect since similar mortality did not occur at 30%. No effect on growth rate was reported at 15%, but a significant decrease in growth was reported at 30%.
<u>Data Quality</u>	
Not assignable – Klimisch Code 4b	
<u>Reference</u>	
Seppanen 1969 as cited in: Anon. 1989. Final report on the safety assessment of tall oil acid. J. Amer. Coll. Toxicol. 8:769-776.	

REPEAT DOSE TOXICITY	
<u>Test substance</u>	
Chemical Name	Tall oil fatty acid
CAS #	61790-12-3
Remarks	This substance is also referred to as TOFA in the test plan for Tall Oil Fatty Acids and Related Substances.
<u>Method</u>	
Method/Guideline followed	Test procedure is consistent with OECD Test Method 407, <i>"Repeat Dose 28-Day Oral Toxicity Study in Rodents"</i>
Year	1969
GLP (Y/N)	N (pre-GLP)
Species	Rat
Strain	Charles River
Sex	Male, female
Route of Administration	Oral, diet
Exposure Period	90 days
Frequency of Treatment	Daily
Post-exposure observation period	None
Dose Levels	5, 10, and 25% (approximately equivalent to 2500, 5000, and 12,500 mg/kg/day)
Control group (Y/N)	Y
<u>Results</u>	
NOEL:	5%, approximately 2500 mg/kg/day
<u>Detailed Summary</u>	
	<p>Tall oil fatty acid was administered to Charles River rats (n = 10/sex/group) in the diet at concentrations 0, 5, 10, or 25% for 90 days. The approximate doses were 0, 2,500, 5,000, or 12,500 mg/kg/day, based on standard conversion factors provided by WHO (1990). Parameters evaluated included clinical signs, mortality, body weight, body weight gain, food consumption, hematology, clinical chemistry, urinalysis, gross pathology, organ weights (liver, kidneys, spleen, gonads, heart, adrenal glands, thyroid gland, brain), and microscopic pathology (esophagus, stomach, small intestine, cecum, colon, liver, kidneys, spleen, pancreas, urinary bladder, pituitary gland, adrenal gland, testes, seminal vesicle, ovary, bone marrow, thyroid gland, parathyroid gland, salivary gland, prostate gland, heart, aorta, lung, lymph node, skeletal muscle, peripheral nerve, bone, spinal cord, uterus, trachea, eye, optic nerve, brain).</p> <p>Two control rats died during blood sampling. No other deaths occurred and no clinical signs were observed. Body weight and body weight gain were not affected by treatment, but food consumption was slightly decreased at 10 and 25%. No changes in hematology, clinical chemistry or urinalysis parameters occurred at any dose. At gross pathology, no treatment-related effects were noted at any dose. No consistent organ weight changes and no histopathological effects were reported at any dose. Based on these data, the NOEL was 5% (approximately 2,500 mg/kg/day).</p>
<u>Data Quality</u>	
	Valid without restriction – Klimisch Code 1b
<u>References</u>	
	Fancher, O.E. 1969. Ninety-day subacute oral toxicity of [trade name deleted; tall oil fatty acid] in albino rats. IBT No. B7067. Industrial Bio-Test Laboratories, Inc., Northbrook, Illinois.

	World Health Organization (WHO). 1990. Principles for the Toxicological Assessment of Pesticide Residues in Food.
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IN VITRO GENETIC TOXICITY	
<u>Test substance</u>	
Chemical Name	Tall oil fatty acid
CAS #	61790-12-3
Remarks	This substance is also referred to as TOFA in the test plan for Tall Oil Fatty Acids and Related Substances.
<u>Method</u>	
Method/Guideline followed	Test was consistent with OECD Test Method 471, " <i>Bacterial Reverse Mutation Test</i> "
Year	1984
GLP (Y/N)	Y
System of testing	<i>S. typhimurium</i> strains TA98, TA100, TA1535, TA1537, TA1538
Concentration	0, 100, 333, 1000, 3333, 10000 µg/plate
Metabolic activation	With and without addition of S-9 fraction from Aroclor 1254-treated Sprague-Dawley rats.
Results	Non-mutagenic
<u>Detailed Summary</u>	Tall oil fatty acid was tested against <i>S. typhimurium</i> strains TA98, TA100, TA1535, TA1537 and TA1538 for mutagenic activity. The test article was tested at concentrations of 100, 333, 1000, 3333 and 10,000 µg/plate with and without metabolic activation. Positive controls not requiring metabolic activation included sodium azide, 9-aminoacridine and 2-nitrofluorene; the positive control requiring metabolic activation was 2-aminoanthracene. No increases in mutation frequency were reported at any concentration of tall oil fatty acid with or without metabolic activation. Tall oil fatty acid was not mutagenic in this assay.
<u>Data Quality</u>	Valid without restriction – Klimisch Code 1a
<u>Reference</u>	Godek, E.G. 1983. Ames Salmonella/microsome plate test: fatty acid [trade name deleted]. Study No. PH 301D-AC-018-83. Pharmakon Research International, Inc., Waverly, Pennsylvania.

REPRODUCTION AND DEVELOPMENTAL TOXICITY	
<u>Test substance</u>	
Chemical Name	Tall oil fatty acid
CAS #	61790-12-3
Remarks	This substance is also referred to as TOFA in the test plan for Tall Oil Fatty Acids and Related Substances.
<u>Method</u>	
Method/Guideline followed	Test procedure was consistent with OECD Test Method 416, "Two-Generation Reproduction Toxicity Study" with one exception: the initial treatment period was decreased (three weeks versus ten weeks).
Year	1975
GLP (Y/N)	N
Species	Rat
Strain	Sprague-Dawley
Sex	Male and female
Route of Administration	Oral, diet
Frequency of Treatment	Daily
Dose	5 and 10% (approximately equivalent to 2500 and 5000 mg/kg/day)
Control group (Y/N)	Y
Pre-mating exposure period for males	20 days (parental generation)
Pre-mating exposure period for females	20 days (parental generation)
<u>Results</u>	
NOEL	10%, approximately 5000 mg/kg/day, for reproductive and systemic toxicity
<u>Detailed Summary</u>	
<p>Sprague-Dawley rats (n = 30 females/group and 15 males/group) were administered tall oil fatty acid (CAS #61790-12-3) in the diet at concentrations of 0, 5 or 10%. The approximate doses were 0, 2,500, or 5,000 mg/kg/day, based on standard conversion factors provided by WHO (1990). The parental (F₀) generation began treatment at 80 days of age and were mated at 100 days of age. Treatment continued through the weaning of the first generation (F₁). After weaning, 20 F₁ males and 20 F₁ females per group were maintained on the parental diet. At 100 days of age, these rats were mated and allowed to deliver pups (F₂). Parameters evaluated included F₁ reproductive parameters, F₁ fertility, viability, lactation, and gestation indices, hematology, serum chemistry, urinalysis, and microscopic pathology of the F₂ pups (brain, pituitary gland, spinal cord, eye, sub-maxillary gland, thyroid, lungs, heart, liver, kidneys, spleen, adrenals, pancreas, stomach, intestines, lymph nodes, bladder, gonads, skin, bone, bone marrow, nerve, muscle).</p> <p>Treatment did not affect the number of liveborn or stillborn F₁ litters and pups, or F₁ weaning weight. No treatment-related changes in fertility, viability, lactation, or gestation indices were measured. Hematology, clinical chemistry and urinalysis parameters were similarly unchanged, and gross and microscopic pathology revealed no treatment-related effects. Tall oil fatty acid had no effect on the reproductive or developmental capabilities of rats at doses as high as 10% (approximately 5,000 mg/kg/day).</p>	

<u>Data Quality</u>	Valid without restriction – Klimisch Code 1b
<u>References</u>	<p>Tegeris, A.S. 1975. Sub-acute reproduction in the rat on tall oil fatty acid [trade name deleted]. Report No. 75-106. Pharmacopathics Research Laboratories, Inc., Laurel, Maryland.</p> <p>World Health Organization (WHO). 1990. Principles for the Toxicological Assessment of Pesticide Residues in Food.</p>

REPRODUCTION AND DEVELOPMENTAL TOXICITY	
<u>Test substance</u>	
Chemical Name	Tall oil fatty acid
CAS #	61790-12-3
Remarks	This substance is also referred to as TOFA in the test plan for Tall Oil Fatty Acids and Related Substances.
<u>Method</u>	
Method/Guideline followed	Test procedure was consistent with OECD Test Method 416, <i>"Two-Generation Reproduction Toxicity Study"</i> with one exception: the initial treatment period was decreased (three weeks versus ten weeks).
Year	1977
GLP (Y/N)	N
Species	Rat
Strain	Sprague-Dawley
Sex	Male and female
Route of Administration	Oral, diet
Frequency of Treatment	Daily
Dose	5 and 10% (approximately equivalent to 2500 and 5000 mg/kg/day)
Control group (Y/N)	Y
Pre-mating exposure period for males	20 days (parental generation)
Pre-mating exposure period for females	20 days (parental generation)
<u>Results</u>	
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	similarly unchanged, organ weights were unchanged, and gross and microscopic pathology revealed no treatment-related effects. Tall oil fatty acid had no effect on the reproductive or developmental capabilities of rats at doses as high as 10% (approximately 5,000 mg/kg/day).
<u>Data Quality</u>	Valid without restriction – Klimisch Code 1b
<u>References</u>	<p>Tegeris, A.S. 1977. Tall oil fatty acid: two-generation reproduction study in the rat. Report No. 77-124. Pharmacopathics Research Laboratories, Inc., Laurel, Maryland.</p> <p>World Health Organization (WHO). 1990. Principles for the Toxicological Assessment of Pesticide Residues in Food.</p>